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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,221	02/16/2001	Doris Hubler	JENA 3	7076

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EXAMINER

WEBMAN, EDWARD J

ART UNIT PAPER NUMBER

1616

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/719,221	Applicant(s) HUBLER ET AL.	
	Examiner Edward J. Webman	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/16/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-31 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,7-11,14,17,22-28 and 31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 is/are allowed.
- 6) ☒ Claim(s) 1,2,4,12,13,15,16,18,19,29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/06/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicants previously elected a method of treatment combining a specific androgen, testosterone propionate, with a specific gestagen, dienogest.

Applicant's election with traverse of a method of treating simultaneously testosterone deficiency and benign prostatic hyperplasia in the reply filed on 2/16/05 is acknowledged. The traversal is on the ground(s) that no undue burden has been established. This is not found persuasive because benign prostatic hyperplasia and the non-elected prostatic cancer are diseases requiring separate searches.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 12, 13, 15, 16, 18-20, 29, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hesch et al (US 5,795,883) in view of Shealy et al (US 5,609,617) and Campbell et al (4,702,282).

Hesch et al disclose that it is well known in the art that androgens such as testosterone are useful in methods of treating androgen deficiency in man (column 1, lines 10-16). Such a deficiency is known to cause benign enlargements of the prostate (column 1, lines 46-54). Testosterone propionate is specified (column 1 line 13). However, Hesch et al do not disclose the addition of the claimed gestagen.

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Shealy et al teach that it is known in the art to treat prostatic hypertrophy with DHEA (column 1 lines 43-49). Shealy et al increase serum DHEA levels by topical administration of progesterone, as applicants note (column 3 line 38-42).

Campbell et al teach the topical delivery of drugs such as testosterone and progesterone via a transdermal, a claimed vehicle, with improved release characteristics (abstract). Treatment of testosterone deficiency is disclosed (column 5 lines 14-16).

It would have been obvious to one of ordinary skill to add progesterone to the androgen deficiency treatment disclosed by Hesch et al to achieve the beneficial effect of treating the accompanying enlargement of the prostate by increasing serum DHEA levels in view of Shealy et al. As to the topical delivery taught by Shealy et al, it would have been additionally obvious to one of ordinary skill to use the topical vehicle of Campbell et al for such delivery to achieve the beneficial effect of improved release characteristics.

As to the claimed ranges of androgen and gestagen dosages, it is within the skill of the art to select optimal parameters such as ratios, ranges of doses or weight percents of components in order to achieve a beneficial effect. See In re Boesch, 205 USPQ 215 (CCPA 1980). Therefore, the ratios, ranges of doses or weight percents instantly claimed are not considered critical absent evidence showing unexpected and superior results.

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Claims 4, 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 4, 13 (and, the examiner observes, nonelected claim 14) "levonorgestrel" appears twice, rendering the claim vague. Further, the "or" preceding the second occurrence of the word in claim 13 (and non-elected claim 14) is redundant.

Claims 1, 2, 4, 12, 13, 15, 16, 18, 19, 29, 30 are rejected.

Claim 20 is allowable over testosterone, the elected androgen, and dienogest, the elected gestagen.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, G. Kunz, can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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